# In the United States Court of Federal Claims

# OFFICE OF SPECIAL MASTERS No. 21-47V

UNPUBLISHED

MARNIE SCHMALTZ,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 22, 2023

Special Processing Unit (SPU); Entitlement to Compensation; Ruling on the Record; Findings of Fact; Influenza ("Flu"); Shoulder Injury Related to Vaccine Administration (SIRVA);

Jessica Anne Olins, Maglio Christopher & Toale, PA, Seattle, WA, for Petitioner.

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

### **RULING ON ENTITLEMENT<sup>1</sup>**

On January 4, 2021, Marnie Schmaltz ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine administered on October 16, 2019. Petition at 2-3. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons set forth below, I find that Petitioner is entitled to compensation.

<sup>&</sup>lt;sup>1</sup> In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>&</sup>lt;sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

### I. Relevant Procedural History

After the claim's initiation, Respondent filed a Rule 4(c) Report opposing compensation. Rule 4(c) Report (ECF No. 26) at 6-16. Petitioner filed a motion for a ruling on the record with regard to entitlement on August 22, 2022. Memorandum of Law in Support of Findings of Fact and Conclusions of Law ("Mot."), ECF No. 31. Respondent opposed the motion on October 27, 2022, arguing that Petitioner does not meet the severity requirement of the Vaccine Act and does not establish that she suffered a Table injury. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 34, at 6-10. Petitioner filed a reply on October 14, 2022. Reply to Respondent's Response to Petitioner's Motion for Findings of Fact and Conclusions of Law ("Reply"), ECF No. 36.

#### II. Petitioner's Medical Records

Petitioner received a flu vaccine in her left shoulder on October 16, 2019. Ex. 9 at 2. She had no history of prior left shoulder pain or issues. Ex. 4 at 23. Almost two weeks later, on October 29, 2019, Petitioner presented to her primary care physician with complaints of left shoulder pain that was "shooting pain down her arm and fingers" since receiving her flu vaccine. Ex. 4 at 15. She was diagnosed with impingement syndrome and possibly an injury to the supraspinatus. *Id.* at 16.

Petitioner underwent an MRI on November 8, 2019. Ex. 4 at 31. The MRI showed hypertrophic changes of the acromioclavicular joint, fluid in the bursa compatible with bursitis, mild tendinosis, and glenohumeral joint effusion. Ex. 4 at 31.

On November 18, 2019, Petitioner had an initial orthopedic evaluation of her left shoulder with Dr. Kurt Hirshorn. Ex. 2 at 16. She stated that her shoulder was "bothering her" "ever since she had this [flu] shot". *Id.* The orthopedist noted that Petitioner's MRI showed impingement along with structural tears. *Id.* at 17. She was diagnosed with impingement syndrome, prescribed prednisone, and received a steroid injection. *Id.* at 18.

Petitioner began physical therapy on December 16, 2019. Ex. 2 at 14. At that time, she reported pain in her shoulder, numbness, tingling in her left fingertips, and hypersensitivity to cold. *Id.* Petitioner attended three physical therapy sessions between December 16 and January 16, 2020. At her final physical therapy sessions, she reported that she was doing better and had considerably less pain. *Id.* at 10-12.

Petitioner was next seen on January 21, 2020, by her orthopedist. Ex. 2 at 9. She reported that the subacromial injection had worn off and she had constant aching, popping, and snapping in her left shoulder. *Id.* She was diagnosed with persistent subacromial impingement and was recommended to undergo surgical intervention.

On March 3, 2020, Petitioner underwent a breast mammogram and ultrasound. Ex. 4 at 29. There is no record of reports of shoulder pain. *Id.* Three weeks later, Petitioner presented to her primary care physician complaining of sore throat, headache, fatigue, and diarrhea. Ex. 4 at 11. There is no indication that Petitioner mentioned shoulder pain at that time.

There is a subsequent eighteen-months gap in the records. On July 12, 2021, Petitioner again sought treatment for her left shoulder from Dr. Hirshorn. Ex. 10 at 6. She reported increased pain over the past couple weeks, and that she may have "aggravated her shoulder at work by doing some heavy lifting." *Id.* The record also states that she did not have much improvement with physical therapy, however the "[p]rior cortisone injection [on] 11/18/2019 did improve her symptoms temporarily." Dr. Hirshorn also noted that Petitioner had "almost a 3 year history of left shoulder pain and dysfunction...." *Id.* at 8. Petitioner received a steroid injection, was diagnosed with impingement, and scheduled a second MRI.

#### III. Declarations

Petitioner submitted two declarations in support of her petitioner. Ex. 7, Ex. 11. Petitioner described the onset of her injury and her course of treatment. Petitioner stated that, during her last physical therapy session, she was advised there was nothing further that could be done until surgical intervention. Further, she had not yet scheduled surgery due to the COVID-19 pandemic. Ex. 7 at 2. In Petitioner's supplemental affidavit, Petitioner stated that her injury still requires surgery, however she cannot currently afford the cost or necessary rehabilitation period. Ex. 1 at 1-2.

Petitioner's daughter, Tiffany Selke, also submitted a declaration in support of this petition. Ex. 13. She further explained the pain her mother experienced and the course of treatment.

#### IV. Fact Findings and Ruling on Entitlement

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the

duration and severity of petitioner's injury, and the lack of other award or settlement,<sup>3</sup> a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

## 42 C.F.R. § 100.3(c)(10).

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally

<sup>&</sup>lt;sup>3</sup> In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.* 

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

#### A. Severity Requirement

The first issue to be resolved is whether Petitioner has demonstrated that she suffered "residual effects or complications of [the injury alleged] for more than six months after the administration of the vaccine," as required for eligibility under the Vaccine Program. Section 11(c)(1)(D)(i).

There is no dispute that Petitioner received the flu vaccine on October 16, 2019, and she therefore must demonstrate by preponderant evidence that her residual symptoms continued at least through April 16, 2020. See, e.g., Herren v. Sec'y of Health & Human Servs., No. 13-100V, 2014 WL 3889070, at \*2 (Fed. Cl. Spec. Mstr. July 18, 2014); see also Hinnefeld v. Sec'y of Health & Human Servs., No. 11-328V, 2012 WL 1608839, at \*4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's Guillain-Barré syndrome resolved less than two months after onset).

The record establishes that Petitioner's initial treatment occurred over approximately three months, between October 29, 2019 and January 21, 2020, followed by an eighteen month gap. However, when she returned for additional treatment she specifically recalled that the earlier cortisone injection received in November 2019

temporarily improved her symptoms, suggesting at some point its effects wore off. Ex. 10 at 7. Further, her orthopedist noted that Petitioner had a long history of left shoulder pain and dysfunction, indicating that she was seeking treatment for the 2019 shoulder injury (although the history length, if literally true, would have begun prior to vaccination).

Respondent argues that Petitioner voluntarily stopped treating her shoulder in January of 2020, and there is no evidence that she was simply waiting to pursue surgical intervention. Opp. at 6-7. Petitioner contends that her gap in treatment was reasonable due to the COVID-19 pandemic, financial hardship, and rehabilitation requirements associated with surgical intervention. Further, she states in her declaration that she was advised additional physical therapy would not be fruitful and surgical intervention was the best path forward. Reply at 3.

Respondent notes in reaction that Petitioner had two intervening medical appointments that did not mention shoulder pain in the winter of 2020. Opp. at 11. The cited appointments were, however, for unrelated medical issues, including an urgent care visit and a gynecology exam. It is understandable that she would not mention her shoulder pain during these visits. I also note that the COVID-19 Pandemic began that same latewinter, and is a reasonable explanation for why treatment visits may have ceased for at least some of this time.

The overall record constitutes a barely-sufficient showing of severity to meet the preponderance evidentiary standard. It is likely that Petitioner's symptoms persisted into the spring of 2020, despite the cessation of treatment and subsequent gap. However, not only does such a light history of treatment suggest a mild injury, but the gap is so lengthy that it is difficult to conclude treatment after it pertains to the SIRVA itself. Such considerations will impact damages in this case.

#### B. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

### 1. Petitioner Had No Prior Left Shoulder Condition or Injury

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent does not dispute that Petitioner meets this criterion, and I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her left shoulder that would explain her symptoms.

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# 2. Onset of Petitioner's Injury Occurred within Forty-Eight Hours of her Vaccination

The medical records establishes onset of injury close-in-time to vaccination. Petitioner first sought treatment approximately on October 29, 2019, less than two weeks after her vaccination, with complaints of shoulder pain since receiving the flu shot. Ex. 4 at 15.

#### 3. Petitioner's Pain was Limited to her Left Shoulder

Respondent claims that Petitioner cannot establish that her pain was limited to her shoulder because she also reported neurological symptoms such as numbness and tingling in the fingers of her left hand. Opp. at 9-10. While Respondent's argument has merit, it ultimately fails to rebut Petitioner's Table showing.

The record contains two reports of non-shoulder pain complaints, but also consistently identifies shoulder pain in Petitioner's left shoulder. Ex. 2 at 15, Ex. 4 at 15. Petitioner's complaints, and the diagnoses, are also focused on the shoulder. See, e.g., Ex. 4 at 15 (October 29, 2019, record diagnosing Petitioner with impingement syndrome).

Admittedly, pain reported in Petitioner's arm and numbness may be unrelated to Petitioner's SIRVA – but that kind of complaint or injury can be addressed when calculating damages. The mere existence of such record complaints does not defeat a showing that Petitioner not only did experience shoulder-specific pain, but that most of her complaints and treatment efforts were aimed at that. Accordingly, preponderant evidence supports this Table element as well.

#### 4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent does not contest this aspect of Petitioner's claim, and there is nothing in the records to suggest that any such condition or abnormality exists.

#### C. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received a flu vaccine intramuscularly on October 16, 2019, 2019, in the United States. Ex. 9 at 2; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for his injury. Ex. 8; Section 11(c)(1)(E) (lack of prior civil award).

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

#### Conclusion

In view of the record, I find preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA, and that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master